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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,351	09/14/2005	Catharina Everdina Hissink	05032-00100	9053
22910	7590	11/19/2009		EXAMINER
BANNER & WITCOFF, LTD.				SU, SUSAN SHAN
28 STATE STREET			ART UNIT	PAPER NUMBER
SUITE 1800				3761
BOSTON, MA 02109-1701				
			MAIL DATE	DELIVERY MODE
			11/19/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/532,351	<b>Applicant(s)</b> HISSINK ET AL.
	<b>Examiner</b> SUSAN SU	<b>Art Unit</b> 3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 06 July 2009.  
 2a) This action is FINAL.      2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-39 is/are pending in the application.  
 4a) Of the above claim(s) 8-26 and 36 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-7,27-35 and 37-39 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_

4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date \_\_\_\_\_

5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_

**DETAILED ACTION**

***Status of Claims***

Claims 1-39 are pending, of which Claims 1, 2, 6, 7, 27, 30, 34, and 39 are amended and Claims 8-26 and 36 are withdrawn. Claim 40 is canceled. No new matter is added.

***Response to Arguments***

1. Applicant's arguments filed July 6, 2009 have been fully considered but they are not persuasive. Applicant argues that Hahn does not teach an elastic polymer and cites portions of Hahn's disclosure to suggest that the material used in Hahn is much more rigid than the claimed drain material. However, as explained in the Office Action dated January 5, 2009, Hahn teaches that the catheter, which is capable of being used as a drain, comprises lactide polyester, which is positively claimed in claim 5 by the Applicant, thus the Hahn device necessarily exhibits the claimed material properties. The rejection was made in view of *in re Spada* or *in re Fitzgerald*. It is held that the discovery of a new property for a previously known composition cannot impart patentability of the known composition. See *in re Spada*, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990); Titanium Metals Corp. of Am. v. Banner, 778 F 2d. at 780, 227 USPQ at 777-778. When the structure or composition recited in the reference is substantially identical to that of the claims of the instant invention, claimed properties or functions are presumed to be inherent (MPEP 2112-2112.01). A *prima facie* case of either anticipation or obviousness has been established when the reference discloses all the limitations of a claim except for a property or function of

having a specific value and the examiner cannot determine whether or not the reference inherently possesses properties that anticipate or render obvious the claimed invention but has a basis for shifting the burden of proof to the Applicant, as per *in re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980). Therefore the polylactide drain taught by the reference would inherently exhibit the same softening point and elastic modulus as claimed by the Applicant.

2. In response to applicant's argument that the examiner's conclusion of obviousness (i.e. modifying length and thickness of the Hahn device) is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In the instant case, Hahn has indicated that a bioabsorbable device (10) inserted into the body should have a limit in size to minimize pain of putting the device into the patient, while the inner diameter should be sized according to the desired flow rate of the fluid through the device (Col. 3 lines 43-58).

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-5, 28, 32, & 37 are rejected under 35 U.S.C. 102(b) for being anticipated by Hahn et al (US 5,129,889, "Hahn").

With regard to Claims 1 & 3-5, Hahn teaches a drain (an epidural catheter is certainly capable of acting as a drain) suitable for draining a human or animal antrum, organ or tissue, characterized in that it comprises an elastic biocompatible, biodegradable synthetic polymer, which polymer has at least one softening point (glass transition temperature) of at most mammalian body temperature. Hahn teaches that the drain comprises polymer such as polylactides, polyglycolides, and polybutyrates (Col. 4 lines 3-20). The specific softening point and elastic modulus of the polymer are held to be material properties of lactide polyester (polylactides, which is anticipated by Hahn). See MPEP 2112.01 I. As explained in the Response to Arguments, the burden thus shifts to the Applicant to show that the claimed device and the prior art are not substantially identical. Since polyether is optional, it is not given patentable weight in the instant claim.

With regard to Claim 2, Hahn also teaches that the drain consists essentially of said synthetic biodegradable polymer.

With regard to Claim 28, Hahn also teaches that the drain is provided with perforations (Col. 4 lines 63).

With regard to Claim 32, Hahn also teaches that the outer diameter of the drain is 0.5 to 50mm (see Claim 1 of Hahn).

With regard to Claim 37, Hahn teaches a method comprising introducing (see Fig. 3) a drain according to claim 1 in said antrum, organ or tissue, such that said antrum, organ or tissue is connected with the environment or another location within the body, after which said drain degrades over time (Col. 4 lines 25-30) and degradation products of said drain are cleared through the digestive channel and/or said antrum, organ or tissue and/or absorbed (Col. 4 line 21) and subsequently metabolized and/or secreted by the body. The language of “treating a disorder associated with dysfunction of natural drainage of body fluids from an antrum, organ or tissue” is in the preamble and is held to be functional language. Since Hahn teaches the steps of using the drain, it obviously also functions as claimed.

5. Claim 35 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hahn.

Claim 35 is a product-by-process claim. As explained in the MPEP, the patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). In the instant case, the drain as defined in Claim 1 has been shown to be the same as that of prior art. Although a process of production for the drain has not been disclosed by Hahn (and therefore may be different from that claimed by the Applicant), the burden now shifts to the Applicant to come forward with evidence establishing an unobvious

different between the claimed product and the prior art product. *In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983).

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 6-7, 30-31, 38, & 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hahn.

With regard to Claims 6-7, Hahn teaches that the polyester is a lactide-caprolactone copolyester (Col. 4 lines 9-11). It would require only routine skills in the art to modify Hahn so that the lactide content is 20-75 mol %. It has been held that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation (see MPEP 2144.05 II). It would have been obvious to one of ordinary skill in the art at the time of

the invention to modify Hahn for the purpose of obtaining a polymer that has a desirable structural property and absorbability.

With regard to Claims 30-31, Hahn does not expressly teach the length or thickness of the drain. However, it would require only routine skills in the art to find the optimal length and thickness of the drain so that fluids can be properly drained outside the body and there is large enough of a conduit for the fluids to flow through while the drain is thick enough to withstand the compression from the surrounding body tissues. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Hahn for the purpose of making a drain that would have large enough of a conduit for draining fluids while small enough in size to minimize pain in the patient (see Col. 3 lines 43-58).

With regard to Claim 38, Hahn does not explicitly teach that the disorder is selected from (chronic) sinusitis, inflammation of the middle ear, liver disorders, disorders of the gastro-intestinal tract, tear duct disorder, surgical wound drainage, and thoracic disorder. However, it would require only routine skills in the art to apply a biodegradable tubular member as taught by Hahn into other medical arts such as would drains and for treating inflammation of the middle ear since it is well known that tubular conduits allow for transport of fluids (which allows for delivery of medicament or removal of pus and such). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Hahn for the purpose of using a biodegradable tube in medical applications so that the tube can be left in the tissue or orifice for an extended period of time.

With regard to Claim 39, Hahn does not expressly teach that the drain is introduced using at least one of a form of attachment selected from the group consisting of sealant, suture, and staple. However, it is general knowledge in the art that drains have been anchored in the body by sutures (see Kettenbach, US 6,406,691, Col. 1 line 55 and Col. 2 line 1 for the general level of knowledge in the art). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Hahn for the purpose of preventing the drain from being dislodged inadvertently.

9. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hahn in view of Jackson et al. (US 2003/0134811, "Jackson"). Hahn does not expressly teach that the polymer is loaded with radiopaque fillers or pharmaceutical components. Jackson teaches a polymer for making a nasal stent that has anti-inflammatory agents mixed into the biodegradable polymer. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Hahn with Jackson for the purpose of preventing medical complications after implanting the drain into the patient.

10. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hahn in view of Noda (US 6,669,711). Hahn does not expressly teach that the drain is a nasal drain. Noda teaches a nasal drain made of polymeric material. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Hahn with Noda for the purpose of adapting the drain for multiple medical purposes.

11. Claims 33-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hahn in view of Goldsmith, III (US 5,026,378, "Goldsmith").

Regarding Claim 33, Hahn does not expressly teach a funnel shaped element on at least one end. Goldsmith teaches a drain with a funnel shaped element on at least one end (see Claim 1 of Goldsmith). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Hahn with Goldsmith for the purpose of keeping the drain stably lodged in the body cavity for proper drainage of fluids.

Regarding Claim 34, Hahn and Goldsmith do not expressly teach that the funnel has a length of 2-20mm and a funnel diameter of 3-30mm. However, adjusting the size of a drain and the funnel that keeps the drain inside a body passage would require only routine skills in the art. Furthermore, the size of the drain and the funnel would need to be adjusted based on the patient for optimal comfort. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Hahn and Goldsmith for the purpose of making the drain fit.

### ***Conclusion***

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Grieshaber et al. (US 2002/0013546) teaches a funnel-shaped drain. Zilber (US 4,955,859) teaches a funnel-shaped urinary stent (which serves as a drain by keeping the urethra open). Balbierz et al. (US 5,599,291) teaches a ureteral stent comprises polylactides.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN SU whose telephone number is (571)270-3848. The examiner can normally be reached on M-F 9:00AM-5:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3761

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susan Su/  
Examiner, Art Unit 3761  
/Tatyana Zalukaeva/  
Supervisory Patent Examiner, Art Unit 3761